

# Pharmacopoeias for Beginners

How to work with the compendia

- Including 3 WORKSHOPS on Interpretation of Monographs (API, DP, Biologic)
- Discuss the use in daily practice!

## SPEAKERS:



**Dr Raphael Bar**

*BR Consulting, formerly with Teva, Israel*



**Dr Françoise Muffat**

*Sanofi Pasteur, France*



**Dr Ulrich Reichert**

*Merck, Germany*



**Dr Andreas Trute**

*Roche, Switzerland*



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6-7 November 2019, Heidelberg, Germany

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## HIGHLIGHTS:

- About the World Pharmacopoeias (including Chinese and other international Pharmacopoeias)
- General Notices: Legal status, structure, importance
- General Chapters / General Texts/ General Monographs
- Compendial testing / Compendial chromatography / Common Pharmacopoeial Tests
- Structure of USP and Ph. Eur. Monographs
- Workshop: Hands on Interpretation of 3 USP and Ph. Eur. Monographs
- ICH Guidelines and their incorporation into the Ph. Eur.



# Pharmacopoeias for Beginners - How to work with the compendia

6-7 November 2019, Heidelberg, Germany

## Objectives

When working with the compendia questions that often arise are: When do General Texts apply? What is mandatory / what is flexible? How to implement a compendial procedure? How to handle pharmacopoeial reference standards? This Education Course will provide you with support to successfully work with the compendia. The course also includes three interactive workshops and aims at systematically acquainting the participants with:

- The structure and activities of the USP and Ph. Eur. organization bodies, and other international Pharmacopoeias (including Chinese Pharmacopoeia)
- Structure of typical monographs
- General chapters on compendial methodologies
- General approach to compendial testing
- Interpreting all tests listed in a monograph
- Handling pharmacopoeial reference standards
- Implementing a compendial procedure described in a monograph
- Fundamentals of compendial chromatography
- Proper use of analytical balances and weighing
- Qualification of laboratory instruments

## Background

US and European pharmacopoeias are independent organizations that set the standards for determining the quality of pharmaceutical products marketed in the US or Europe. These standards govern the quality, strength, purity and potency of active pharmaceutical ingredients, dosage forms and excipients as well as many reagents and solutions used to test these materials.

However, sometimes the pharmacopoeias differ in the quality requirements for the same product or raw material. Compliance, therefore, becomes a major challenge for pharmaceutical companies.

USP-NF standards deemed official by USP are enforceable by the U.S. Food and Drug Administration for medicines manufactured and marketed in the United States and they are recognized and used in more than 130 countries around the globe. The Ph. Eur. is legally binding in 38 European countries and used in over 100 countries worldwide. No wonder then that both pharmacopoeias are widely used by the pharmaceutical industry. Any pharmaceutical testing laboratory must be capable of applying the tests described in the compendial monographs.

In addition, pharmacopoeias are part of the regulations that QPs (Qualified Persons) must comply with for the release of the products as described in the registration dossiers. They also need to manage them in a more and more globalized environment. Therefore, visibility on the on-going drafts and/or work program could be useful for anticipation.

## Target Audience

This course is tailored to beginners and newcomers to pharmaceutical analysis in a regulated laboratory as well as experienced personnel who wish to learn about the recent changes introduced in the USP and Ph. Eur. Furthermore, the course is useful for R&D Laboratory data analysts utilizing pharmacopoeial tests, QA involved in reviewing analytical data, and RA personnel who wish to learn about the pharmacopoeial quality standards

## Moderator

Dr Raphael Bar

## Programme

### About the World Pharmacopoeias

- World Pharmacopoeias: Ph. Eur., USP, Chinese Ph., other international Pharmacopoeias
- Structure of Ph. Eur. and Ph. Eur. on line
- Structure of USP and USP on line
- Chinese & other International Pharmacopoeias
- Pharmacopoeial Forum, Pharmeuropa
- Harmonization between Pharmacopoeias

### General Notices

- Why they are important
- General notices of Ph. Eur., General notices of USP, Alternative procedures, ...

### General Chapters / General Texts / General Monographs

- USP
- Ph. Eur.
- What is mandatory?
- What is flexible?
- When is an article of pharmacopoeial quality?

### Structure of USP and Ph. Eur. Monographs

- Examples for Monographs
- Technical and style guides
- Knowledge database

### WORKSHOPS

Hands on Interpretation of USP and Ph. Eur. monographs of:

- An active substance
- A finished drug product
- A biologic

### Balances and analytical weighing

- USP Chapters <41>, <1251>
- Determination of Repeatability and accuracy of balances
- Determination of minimum weight
- From volumetric to gravimetric sample preparation

## Introduction into Analytical Instrument Qualification according to Ph. Eur. and USP

- USP General Chapter <1058> Analytical Instrument Qualification
- Type of instruments and risk assessment
- Qualification steps: URS, DQ, IQ, OQ and PQ

## Reagents, Solutions & Pharmacopoeial reference standards

- USP and Ph. Eur. requirements for reagents
- Types of solutions (test vs. volumetric solutions)
- Types of reference standards
- USP reference standards
- Ph. Eur. and BP reference standards
- Qualification of secondary reference standard
- Re-use of reference standards?

## Compendial Testing Approach

- The four categories of USP tests
- Verification / Validation of compendial procedures
- Singlet testing
- Reportable result
- When is an article of pharmacopoeial quality?

## Frequently applied Pharmacopoeial Methods

Pharmacopoeial requirements on tests such as

- Clarity and colour of solution
- pH
- KF titration (validation)
- Frequent wet chemistry tests

## Compendial chromatography

- Chapter <621> and Ph. Eur. 2.2.46
- System suitability requirements
- Quantitation of impurities
- Adjustments of method parameters
- Strategies to demonstrate pharmacopoeial compliance

## ICH Guidelines and their incorporation into the Ph. Eur., with a focus on the Impurity guidelines

- ICH Q3A on Drug Substance Related Impurities
- ICH Q3B on Drug Product Degradation Products
- ICH Q3C on Residual Solvents
- ICH Q3D on Elemental Impurities
- ICH M7 on potentially mutagenic Impurities

## Speakers



### Dr Raphael Bar, BR Consulting, Israel

Dr Bar headed the Analytical R&D Laboratories at Teva Pharmaceuticals and the analytical QC laboratory at Pharmos. He served in the Scientific Advisory Board of global PDA (USA) and is presently a board member of Israel PDA Chapter as well as a member of the organizing committee of the Israel Society for Analytical Chemistry. For the last ten years, Raphael Bar has been a pharmaceutical consultant for the Pharma and bio-Pharma industries.



### Dr Françoise Muffat, Sanofi Pasteur, France

Françoise Muffat is a pharmacist who has more than 25 years experience in pharmaceutical industry. She had various positions in Quality, Regulatory Affairs and Pharmaceutical Affairs at Merial (veterinary medicines), Rhône-Poulenc Rorer, Aventis, Sanofi Winthrop Industrie, France (human medicines). She is presently in charge of Pharmacopoeia & Quality Intelligence at Sanofi Pasteur, Lyon, France.



### Dr Ulrich Reichert (M.D.R.A.), Merck, Germany

Dr Reichert is Head of Pharma and Food Materials in the Regulatory Management organization of Merck Life Science. He is, amongst other things, responsible for the preparation of regulatory dossiers for pharmaceutical starting materials (Master Files). He is experienced in regulatory requirements and analytical methods for pharmaceutical raw materials and member of Ph. Eur. expert groups at the EDQM.



### Dr Andreas Trute, Roche, Switzerland

Dr Trute is a pharmacist and received his Ph.D. in pharmaceutical biology from the University of Münster, Germany. He worked in several QA positions at Novartis Pharma AG, Switzerland (for solid formulations) and Roche Diagnostics GmbH, Penzberg, Germany (for biotech APIs). Since 2014, Dr Trute is working for F. Hoffmann-La Roche, Basel, Switzerland. He is deputy Responsible Person (Switzerland) for Investigational Medicinal Products (IMPs).

## Heidelberg – Optimal Accessibility via Frankfurt

As one of the most beautiful cities in Europe, Heidelberg is at first sight an interesting venue – but is it also easily accessible? The answer is: Yes! The connection to Frankfurt Airport is convenient and fast. It takes only about 45 minutes to get from Frankfurt to Heidelberg.

TLS: <https://www.tls-heidelberg.de/en/>

Lufthansa Airport Shuttle: <https://frankfurt-airport-shuttles.palisis.com/?locale=en>

HLS: <http://www.hls-online.com/PCS-Flughafentransfer.html>

Train: You can also take a train to get from/to the airport, which takes less than one hour.

<https://www.bahn.com/en/view/index.shtml>



Reservation Form (Please complete in full)

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 P.O. Box 101764  
 Fax +49 (0) 62 21/84 44 34

**D-69007 Heidelberg**  
**GERMANY**

**General terms and conditions**

If you cannot attend the conference you have two options:

1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation

- until 2 weeks prior to the conference 10 %

- until 1 week prior to the conference 50 %

- within 1 week prior to the conference 100 %

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 German law shall apply. Court of jurisdiction is Heidelberg.

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**Date**

Wednesday, 6 November 2019, 09:00 h – 17:45 h  
 (Registration and coffee from 08:30 h – 09:00 h)  
 Thursday, 7 November 2019, 08:00 h – approx. 16:15 h

**Venue**

Heidelberg Marriott Hotel  
 Vangerowstrasse 16  
 69115 Heidelberg, Germany  
 Phone +49 (0)6221 – 908 0  
 Info.heidelberg@marriott.com

**Fees (per delegate plus VAT)**

ECA Members € 1,590  
 APIC Members € 1,690  
 Non-ECA Members € 1,790  
 EU GMP Inspectorates € 895  
 The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments.  
 VAT is reclaimable.

**Accommodation**

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the event. Reservation should be made directly with the hotel. Early reservation is recommended.

**Social Event**

In the evening of the first course day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

**Registration**

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

**Conference language**

The official conference language will be English.

**Organisation and Contact**

ECA has entrusted Concept Heidelberg with the organisation of this event.  
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